K123901

510(k) SUMMARY

Tractus TissueMapper Reviewer Application

JAN 29 2013

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Tractus Corporation

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Date Prepared: January 23, 2013

Name of Device and Name/Address of Sponsor

TissueMapper Reviewer Application

Tractus Corporation

981 El Cajon Drive

Danville, CA 94526

Common or Usual Name: Picture Archiving and Communications System

Regulation Number: 21 CFR 892.2050

Product Code: LLZ

Device Class: Class II

Predicate Devices

Sentinelle Medical Aegis Navigation Application (K093672)

Intended Use / Indications for Use:

The Tractus TissueMapper Reviewer Application provides two and three-dimensional image review, manipulation, and analysis tools to assist users in screening, diagnosis, planning and performing image-guided interventional procedures. The supported imaging modality is Ultrasound (US). Images and data are received from various imaging systems and other sources such as calibrated spatial positioning devices.

This device provides the capability to overlay annotations on 2D or 3D medical image displays. These annotations may represent the position of instruments including but not limited to imaging probes or other tracked devices.

This device is intended to assist skilled medical professionals in clinical screening and interventions, for anatomical structures where imaging is currently used for visualizing such structures, including head and neck, breast, thoracic, and abdominal applications.

Technological Characteristics

The **TissueMapper** Reviewer Application consists of:

- the Tractus TissueMapper Reviewer Application software

The TissueMapper Reviewer Application is an electronic image review and reporting software program intended to operate on a Windows Operating System (OS) computer. The device allows the review of previously recorded ultrasound examinations which are performed using standard ultrasound systems and other sources such as calibrated spatial positioning devices, the images of which were recorded digitally.

The images are displayed on a computer monitor. The images may be reviewed individually or as a self-playing sequence (video clip). Certain image functions may be adjusted by the software, such as image brightness, image contrast and image size magnification or reduction. The speed of the video presentation may be adjusted by the software.

The device software presents sequences of mapped ultrasound images to review previously-recorded hand-held ultrasound examinations, which can be transferred to a computer using a media storage device (USB). Each image is mapped anatomically with respect to a user-identified anatomical landmark, such as the nipple or navel. The image mapping information allows anatomic location of user-identified regions of interest for comparison with other imaging techniques or for procedure planning purposes.

The device software allows the user to measure the size, on two user-defined axes, of the region of interest. The device software allows the user to create and store electronic reports on each region of interest.

The **TissueMapper** Reviewer Application requires two off-the-shelf accessories:

- Off-the-shelf computer (PC) to run the **Tractus TissueMapper Reviewer** Application software, which meets the following requirements:
  - Display
    - ≥140 DPI ± 5%

        - Minimum Resolution of 1920x1080
    - Keyboard and Pointing device
    - Processor speed of ≥ 2.5 GHz
    - Hard drive ≥750 GB
    - RAM ≥ 6 GB
    - Ethernet
    - ≥4 USB 2.0 ports or better
    - UL60950 ITE Compliant
    - Operating System: Windows 7

- Off-the-shelf media storage (USB) to move image files from standard legally marketed ultrasound machines to the off-the-shelf computer noted above

Pursuant to 809.92(a)(6), basically, both the applicant's device ("**Tractus TissueMapper Reviewer Application**") and the predicate device ("**Sentinelle Medical Aegis Navigation Application**"), present previously recorded images that are spatially mapped with calibrated spatial positioning devices for subsequent review, employ electromagnetic sensors to detect the location of an ultrasound transducer for a registration of transducer location with respect to the region of body scanned with ultrasound, allow for review of ultrasound images collected in the course an ultrasound scan and are software products that run on accessory PC computers. The only technological differences between the **Tractus TissueMapper Reviewer Application** and its predicate ("**Sentinelle Medical Aegis Navigation Application**") are: (1) the **TissueMapper Reviewer Application** is only used with the imaging modality of Ultrasound; (2) the **TissueMapper Reviewer Application** is used to identify and map regions of interest for planning subsequent non-invasive diagnostic examinations, such as a diagnostic X-Ray, diagnostic ultrasound, or MRI, where the Sentinelle Medical Aegis Navigation Application may be also used to overlay instrument templates for planning interventional procedures, such as biopsy. Both the applicant's device ("Tractus TissueMapper Reviewer Application") and the predicate device ("Sentinelle Medical Aegis Navigation Application") are software devices that have a Moderate Level of Concern.

The Tractus TissueMapper Reviewer Application software is Safety Class B according to ANSI/AAMI/IEC 62304:2006. Determination of the LOC and Safety Class is the result of risk assessment activities per ISO 14971.

TRACTUS CORPORATION

TISSUEMAPPER REVIEWER APPLICATION

SUBSTANTIAL EQUIVALENCE CHART

	[Tractus TissueMapper Reviewer Application, k123901]	[Sentinelle Medical Aegis Navigation Application, k093672]
Intended Use	***The Tractus TissueMapper Application Software*** provides two and three-dimensional image review, manipulation, and analysis tools to assist users in screening, diagnosis, planning and performing image-guided interventional procedures. The supported imaging modality is Ultrasound (US). Images and data are received from various imaging systems and other sources such as calibrated spatial positioning devices. This device provides the capability to overlay annotations on 2D or 3D medical image displays. These annotations may represent the position of instruments including but not limited to imaging probes or other tracked devices. This device is intended to assist skilled medical professionals in clinical screening and interventions, for anatomical structures where imaging is currently used for visualizing such structures, including head and neck, breast, thoracic, and abdominal applications.	This device provides two and three-dimensional image review, manipulation, and analysis tools to assist users in screening, diagnosis, planning and performing image-guided interventional procedures. Supported imaging modalities include Magnetic Resonance (MR), Ultrasound (US), Single Photon Emission Computed Tomography (SPECT), Computed Tomography (CT), Positron Emission Tomography (PET), Fluoroscopy and Endoscopy. Images and data are received from various imaging systems and other sources such as calibrated spatial positioning devices. This device provides the capability to overlay annotations on 2D or 3D medical image displays. These annotations may represent the position of instruments including but not limited to biopsy needles, guidance wires, imaging probes or other tracked devices. This device is intended to assist skilled medical professionals in clinical screening and interventions, for anatomical structures where imaging is currently used for visualizing such structures, including head and neck, breast, thoracic, and abdominal applications (including pelvis). Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image

		interpretations. Mammographic images may only be interpreted using a FDA approved monitor that offers at least 5 MPixel resolution and meets other technical specifications reviewed and accepted by the FDA.
Indications for Use	Same as above	Same as above
User Population	Skilled medical professionals	Skilled medical professionals
Technological Characteristics	System, Image Processing, Radiological; Picture Archiving and Communications System	System, Image Processing, Radiological; Picture Archiving and Communications System
Primary component(s)	Software: TissueMapper Reviewer Application	Software: Aegis Navigation Application
Accessories (if any)	Computer (PC) and storage media (USB)	Not specified in 510(k), assumed to include computer to run software and some type of media or method to transmit files to computer
Safety Features	Software risk analysis developed in accordance with ISO 14971	Not available in 510(k)
Software	Yes	Yes
3-D Rendering	Yes	Yes
Regions of Interest – Location	Yes	Yes
Regions of Interest – Annotation	Yes	Yes
Supported Imaging Modalities	Ultrasound	MRI, Ultrasound, SPECT, CT, Fluoroscopy, and Endoscopy.
Software level of concern	Moderate level of concern	Moderate level of concern
Standards with which the Device Complies	None required	Not available in 510(k)

Performance Data

Testing for TissueMapper Reviewer Application was performed to ensure that all functional requirements have been met, and that core functions execute as expected. Testing was conducted in-house by trained personnel in a simulated work-environment using phantoms to obtain the functional and accuracy test results. Registration accuracy tests were performed to ensure that the registration and correspondence between ultrasound meets or exceeds specified criteria. The test methodology employed was identical to that of the Aegis predicate device, conducted by targeting locations within a phantom and confirming that the selected target location based on the registration calculation is within the same tolerance range or better than the Aegis predicate device. System Validation Testing of the Tractus TissueMapper Reviewer Application was performed on a two breast phantoms with 11 masses total randomly positioned. All 11 of the masses were successfully identified.

The results of these tests demonstrate that the TissueMapper Reviewer Application validation is within specification.

As such, TissueMapper Reviewer is as safe and effective as the predicate devices and is substantially equivalent to existing products on the market today. The software performs as well as, or better than legally marketed predicate devices.

Tractus' TissueMapper Reviewer Application indications for use are drawn from the indications for use of a legally marketed predicate device: Sentinelle's Aegis Navigation Application. Tractus TissueMapper Reviewer Application draws from features of this predicate device and does not provide novel functionality. As such, the features provided by Tractus TissueMapper Reviewer Application do not in themselves raise new concerns of safety or effectiveness.

In all instances, the **TissueMapper Reviewer Application** functioned as intended and **the operation** observed was as expected.

Substantial Equivalence

> The **TissueMapper Reviewer Application** is as safe and effective as the **Sentinelle Medical Aegis Navigation Application**. The **TissueMapper Reviewer Application** has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the **TissueMapper Reviewer Application** and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the **TissueMapper Reviewer** is as safe and effective as **Sentinelle Medical Aegis Navigation Application** Thus, the **TissueMapper Reviewer Application** is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 29, 2013

Tractus Corporation
%Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K123901
Trade/Device Name: Tractus TissueMapper Reviewer Application
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 14, 2013
Received: January 15, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sean M. Boyd -S for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k123901

Device Name: Tractus TissueMapper Reviewer Application

Indications for Use:

The Tractus TissueMapper Reviewer Application provides two and three-dimensional image review, manipulation, and analysis tools to assist users in screening, diagnosis, planning and performing image-guided interventional procedures. The supported imaging modality is Ultrasound (US). Images and data are received from various imaging systems and other sources such as calibrated spatial positioning devices.

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Prescription Use ___x____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Sean M. Boyd -S

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K123901